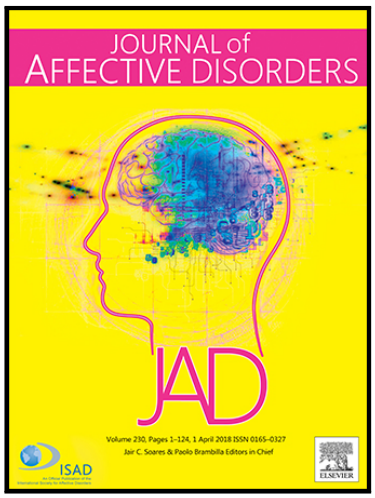
DOI:
10.1016/j.jad.2018.04.025

Document Version
Peer reviewed version



Treatment as usual (TAU) as a control condition in trials of cognitive behavioural-based psychotherapy for self-harm: Impact of content and quality on outcomes in a systematic review

Katrina Witt , Daniela Pache de Moraes , Tatiana Taylor Salisbury , Ella Arensman , David Gunnell , Philip Hazell , Ellen Townsend , Kees van Heeringen , Keith Hawton

PII: S0165-0327(17)32387-X
DOI: 10.1016/j.jad.2018.04.025
Reference: JAD 9679

To appear in: *Journal of Affective Disorders*

Received date: 20 November 2017
Revised date: 27 February 2018
Accepted date: 2 April 2018

Please cite this article as: Katrina Witt , Daniela Pache de Moraes , Tatiana Taylor Salisbury , Ella Arensman , David Gunnell , Philip Hazell , Ellen Townsend , Kees van Heeringen , Keith Hawton , Treatment as usual (TAU) as a control condition in trials of cognitive behavioural-based psychotherapy for self-harm: Impact of content and quality on outcomes in a systematic review, *Journal of Affective Disorders* (2018), doi: 10.1016/j.jad.2018.04.025

HIGHLIGHTS

- Although CBT-based psychotherapy was strongly associated with a significant treatment effect for repetition of self-harm when compared to an unclear TAU condition, the effect size was reduced when compared to multidisciplinary TAU.
- No significant subgroup differences as a result of TAU content or reporting quality were observed for the secondary outcome measures of depression, hopelessness, and suicidal ideation.
- In few trials were details provided of the treatment components offered to participants allocated to the TAU condition. In fewer still was the number of treatment sessions attended by control participants reported. Additionally, and particularly importantly, no author provided a detailed break-down of the treatments actually received by participants in the TAU condition.
- In order to improve the overall quality of trials of psychological interventions researchers should carefully describe both the nature of TAU and what participants in this condition actually receive.

Treatment as usual (TAU) as a control condition in trials of cognitive behavioural-based psychotherapy for self-harm: Impact of content and quality on outcomes in a systematic review

Katrina Witt (D.Phil);[1] Daniela Pache de Moraes (MD);[2] Tatiana Taylor Salisbury;[3,4] Ella Arensman (PhD);[5] David Gunnell (FMedSci);[6] Philip Hazell (PhD);[7] Ellen Townsend (PhD);[8] Kees van Heeringen (PhD);[9] Keith Hawton (FMedSci)[1,*]

[1] Centre for Suicide Research, Department of Psychiatry, University of Oxford, Oxford, UK.
[2] Discipline of Medicine, Pontifícia Universidade Católica do Paraná, Brazil.
[3] Institute of Psychiatry, Psychology and Neurology, King's College London, London, UK.
[4] Centre for Global Mental Health, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK.
[5] National Suicide Research Foundation and School of Public Health, University College Cork, Republic of Ireland.
[6] School of Social and Community Medicine, University of Bristol, Bristol, UK.
[7] Discipline of Psychiatry, Sydney Medical School, Sydney, Australia.
[8] Self-Harm Research Group, School of Psychology, University of Nottingham, Nottingham, UK.
[9] Unit for Suicide Research, Department of Psychiatry and Medical Psychology, Gent University, Gent, Belgium.

* Corresponding author:

Professor Keith Hawton.
Centre for Suicide Research, Department of Psychiatry,
Warneford Hospital, Oxford, OX3 7JX, UK.
Phone: +44 (0)1865 902285
Email: keith.hawton@psych.ox.ac.uk

Word count: 4,473.

ABSTRACT

Background: Randomized controlled trials (RCTs) are the mainstay of evaluations of the efficacy of psychosocial interventions. In a recent Cochrane systematic review we analysed the efficacy of cognitive behavioural-based psychotherapies compared to treatment as usual (TAU) in adults who self-harm. In this study we examine the content and reporting quality of TAU in these trials and their relationship to outcomes.

Methods: Five electronic databases (CCDANCTR-Studies and References, CENTRAL, MEDLINE, EMBASE, and PsycINFO) were searched for RCTs, indexed between 1 January 1998 and 30 April, 2015, of cognitive-behavioural interventions compared to TAU for adults following a recent (within six months) episode of self-harm. Comparisons were made between outcomes for trials which included different categories of TAU, which were grouped as: multidisciplinary treatment, psychotherapy only, pharmacotherapy only, treatment by primary care physician, minimal contact, or unclear.

Results: 18 trials involving 2,433 participants were included. The content and reporting quality of TAU varied considerably between trials. The apparent effectiveness of cognitive behavioural psychotherapy varied according to TAU reporting quality and content. Specifically, effects in favour of cognitive-behavioural psychotherapy were strongest in trials in which TAU content was not clearly described (Odds Ratio: 0.29, 95% Confidence Interval 0.15 to 0.62; three trials) compared to those in which TAU comprised multidisciplinary treatment (Odds Ratio: 0.79, 95% CI 0.63 to 0.97; 12 trials).

Limitations: The included trials had high risk of bias with respect to participant and clinical personnel blinding, and unclear risk of bias for selective outcome reporting.

Conclusions: TAU content and quality represents an important source of heterogeneity between trials of psychotherapeutic interventions for prevention of self-harm. Before clinical trials begin, researchers should plan to carefully describe both aspects of TAU to improve the overall quality of investigations.

Keywords: self-harm; suicide; clinical trials; treatment as usual; methodology.

INTRODUCTION

Self-harm, defined as intentional self-injury or intentional drug overdoses irrespective of level of suicidal intent or type or degree of motivation (Hawton et al., 2003; NICE, 2011). It is a growing problem in many countries worldwide. In England alone, for example, there are now more than 200,000 emergency department presentations for self-harm each year (Hawton et al., 2007). Self-harm is also frequently repeated. Up to one-quarter of patients who present to hospital following an episode of self-harm will return to the same hospital within one year following a repeat episode (Carroll et al., 2014; Owens et al., 2002). Self-harm is also a significant risk factor for death by suicide (Carroll et al., 2014).

Given the prevalence of self-harm, the frequency with which it is repeated, and its association with suicide, it is important that effective interventions are developed and rigorously evaluated for their effectiveness (Hawton et al., 2016a). Guidelines for the evaluation of complex multicomponent interventions, such as those typically developed for the prevention of self-harm, emphasize the primacy of the randomized controlled trial (RCTs) design as the randomization process can protect against selection bias and other threats to internal validity (Craig et al., 2008). RCTs of psychological interventions for self-harm typically compare the active treatment condition against "treatment as usual" (TAU). However, within psychiatry trials the TAU condition is typically poorly defined (Burns, 2009), despite calls since 1996 to define the components of the TAU condition as precisely as the active intervention condition (Burns and Priebe, 1996).

Complicating matters is the fact that TAU necessarily varies between studies as a result of service-related differences over time. It has been demonstrated, for example, that the apparent effectiveness of assertive community treatment (ACT) has

diminished over time as many of the key features of ACT, particularly with respect to reduced case load and increased service intensity, have come to be integrated into routine community care (Clarke et al., 2000). TAU will also vary between different locations, and especially between different countries. TAU practices can also vary between centres in the case of multicentre trials (Saunders and Smith, 2016), and yet, these differences have generally been ignored in self-harm trials.

Variability in the TAU condition can seriously affect the magnitude of the effect size for the experimental intervention in RCTs of psychosocial interventions. For example, it has been shown that whilst manualized interventions for anxiety and depression (e.g., cognitive behavioural therapy [CBT]) are associated with significant benefits in terms of reduced symptomatology when compared to TAU, this effect is attenuated when limited to RCTs in which TAU contained some component of the active treatment (Wampold et al., 2011). Similar effects have been observed in psychosocial trials for cannabis cessation (Cooper et al., 2015). Effect size attenuation may be particularly likely in RCTs conducted in recent years as CBT has become a standard therapeutic approach included in the training of mental health professionals (Sarin et al., 2011).

Despite these important findings the nature of TAU is rarely investigated as an important source of heterogeneity in meta-analyses of the effectiveness of psychosocial treatments (Van de Wiel et al., 2007; Watts et al., 2015). For this reason, we have investigated the quality of reporting for the control condition in trials of CBT-based therapies for self-harm to highlight the potential impact of the TAU condition on the magnitude of the reported treatment effect for these interventions and to provide guidance on reporting of TAU for future trialists in this area (Watts et al., 2015). This work extends our recent update of the treatment literature on the

effectiveness of psychosocial interventions for self-harm in adults (Hawton et al., 2016a, b), in which we conclude that there is now evidence to support the use of brief (i.e., up to 10 sessions) CBT-based psychotherapy for reducing the proportion of adults who engage in further self-harm and for having other benefits for the emotional well-being of patients.

METHOD

Electronic Search Strategy

We searched for RCTs of psychosocial treatments in adults following a recent (within six months) episode of self-harm indexed in five electronic databases (CCDANCTR-Studies and References, CENTRAL, MEDLINE, EMBASE, and PsycINFO) between 1 January, 1998 and 29 April, 2015 using the electronic search strategy outlined in Supplementary Document SD1. The reference lists of 44 major review papers as well as ten English language specialist suicidology journals were also manually searched and researchers active in the field were contacted to identify unpublished literature inadvertently missed by the electronic search.

Trial Eligibility

RCTs were eligible for inclusion provided they met the following criteria: (1) used random allocation to assign participants to the intervention and control groups; (2) participants were 18 years or older at the point of randomization; (3) all participants had engaged in self-harm (defined as any non-fatal act of self-injury and/or intentional drug overdose irrespective of the extent of suicidal intent or any other type of motivation; Hawton et al., 2003) no more than six months prior to randomization; and (4) the trial evaluated the effectiveness of a CBT-based therapy,

including cognitive behavioural therapy (CBT), problem-solving therapy (PST), or a combination of these, relative to treatment as usual (TAU). Non-English language studies were eligible for inclusion in this review and were translated by native speakers.

Trials were independently screened for inclusion by KW and one of TTS, EA, DG, PH, ET, or KvH. Disagreements were resolved following discussion with KH. Where insufficient information was recorded in the study report to determine eligibility, study authors were contacted to provide additional clarification.

Data Extraction

Outcome data

For quantitative analyses, the primary outcome measure was repetition of self-harm at the six month, twelve month, and final follow-up assessment points. Secondary outcomes included scores for depression, hopelessness, and suicidal ideation at the final follow-up assessment. Quantitative data relating to these outcomes were extracted independently by KW and one of TTS, EA, DG, PH, ET, or KvH. Again disagreements were resolved following discussion with KH. Study authors were contacted to provide additional information where data were either missing or unclear.

To investigate homogeneity of the effect size estimate between studies, we calculated the I^2 statistic, which indicates the percentage of variability in effect sizes between studies resulting from genuine methodological and other differences, rather than chance alone. This statistic can take any value between 0% and 100%, with values greater than 75% conventionally interpreted as indicating substantial levels of between-study variability (Higgins et al., 2003).

TAU content

Information on the content of the TAU condition was assessed independently by KW and DPDM using a standard *pro forma*. Details extracted included definition of the TAU condition and whether any component/s of the active treatment condition was/were available to participants randomized to the TAU condition. Disagreements were resolved following discussion with KH.

TAU was classified as either: (1) multidisciplinary treatment (i.e., comprising both psychological and pharmacological treatment from a range of psychiatric, personality, addictions, and/or other services according to need); (2) psychotherapy only; (3) pharmacotherapy only; (4) treatment by GP/primary care physician only; (5) minimal contact (i.e., psychoeducation, bibliotherapy, or remote contact only); or (6) unclear/not adequately described (Watts et al., 2015).

Risk of Bias Assessment

We also assessed risk of bias for each included trial using the approach favoured by the Cochrane Collaboration (Higgins et al., 2008b). Specifically, each study was rated as at high, unclear, or low risk of bias with respect to the following domains: adequacy of the random sequence generation procedure, adequacy of allocation concealment, and presence of participant and clinical personnel blinding, outcome assessor blinding, incomplete outcome data, selective outcome reporting, and any other bias. We also recorded information on the proportion of participants for whom data on the primary outcome, repetition of self-harm, was lacking at the final follow-up assessment.

For the incomplete outcome data criterion, we rated trials as high risk of bias where there were ≥10% missing data for the primary outcome and data had been analysed according to per protocol principles, and where no method had been used to statistically account for missing data. There was one exception to this. Where the last observation carried forward (LOC) method had been used to account for missing data, we rated these trials as unclear risk of bias for this criterion as the LOC method has been shown to introduce bias (Engles and Diehr, 2003).

Statistical Analyses

Proportions of patients repeating self-harm at the six month, 12 month, and last available follow-up assessment were summarized using the odds ratio (OR) and the accompanying 95% confidence interval (CI). Data for all continuous secondary outcome measures, including depression, hopelessness, and suicidal ideation scores, were assessed using the standard mean difference (SMD) and 95% CI, as recommended by the Cochrane Collaboration (Higgins et al., 2008a), because the studies included in the meta-analysis used a variety of different psychometric measures to assess these outcomes.

Given that departure from the intention-to-treat principle, in which all participants are analysed in the groups to which they had been randomly allocated (Hollis, 1999), is associated with artificial inflation of the effect size estimate in treatment intervention trials (Abraha et al., 2015), where possible we analysed data according to the ITT principle. This approach was not always possible, however, particularly in cases where the outcome relied on patient self-reported data (e.g., depression, hopelessness, and suicidal ideation scores). In these cases we have therefore analysed all available case data. To account for any bias introduced by the

use of these data we have considered the effect of missing data for these outcomes within the text of the review, as recommended by the Cochrane Collaboration (Higgins et al., 2011).

All analyses were undertaken in RevMan for Windows, version 5.3, using the Mantel-Haenszel random effects model for all dichotomous outcomes, and for continuous outcomes, using the inverted variance random effects model. Sub-group analyses to investigate whether the effectiveness of CBT-based interventions would vary as a result of the TAU condition were conducted using the random effects model.

RESULTS

The systematic search outlined in Supplementary Document SD1 retrieved a total of 23,830 citations. An additional 10 trials ongoing at the time of the systematic search were identified through correspondence with researchers in the field. Following de-duplication, the overall figure was reduced to 16,799. A total of 16,538 were excluded following screening, whilst a further 237 were excluded after reviewing the full text. Seven trials were additionally excluded from the present review as they evaluated the effectiveness of a pharmacological intervention, whilst a further 11 trials were excluded as they evaluated an intervention for children and adolescents.

A further 37 trials were excluded from this version of the review as they evaluated a psychosocial intervention other than CBT-based psychotherapy. A total of 18 non-overlapping RCTs comparing CBT-based psychotherapy to TAU were therefore included in this study (Brown et al., 2005; Davidson et al., 2014; Dubois et al., 1999; Evans et al., 1999; Gibbons et al., 1978; Guthrie et al., 2001; Hatcher et al., 2011; Hawton et al., 1987; Husain et al., 2014; McAuliffe et al., 2014; Patsiokas and

Clum, 1985; Salkovskis et al., 1990; Slee et al., 2008; Stewart et al., 2009; Tapolaa et al., 2010; Tyrer et al., 2003; Wei et al., 2013; Weinberg et al., 2006) (Figure 1).

Study Characteristics

The included trials comprised a total of 2,433 participants. Of the 13 trials that recorded information on age, the weighted average age at randomization was 29.6 (*SD* 8.3; range 15.0 to 66.0) years. Of the 16 trials that recorded information on gender, 62.5% (*n*=1,833) of participants were female. All participants had engaged in at least one episode of SH in the six months prior to randomization. Further characteristics of these 18 studies can be found in Table 1.

The majority of these 18 trials were conducted in the United Kingdom (*N*=7; (Davidson et al., 2014; Evans et al., 1999; Gibbons et al., 1978; Guthrie et al., 2001; Hawton et al., 1987; Salkovskis et al., 1990; Tyrer et al., 2003) followed by the United States of America (*N*=3; (Brown et al., 2005; Patsiokas and Clum, 1985; Weinberg et al., 2006) with one trial each from Australia (Stewart et al., 2009), China (Wei et al., 2013), Finland (Tapolaa et al., 2010), France (Dubois et al., 1999), The Netherlands (Slee et al., 2008), New Zealand (Hatcher et al., 2011), Pakistan (Husain et al., 2014), and the Republic of Ireland (McAuliffe et al., 2014).

Methodological Quality

The included trials had high risk of bias. All trials were rated as at high risk of bias with respect to participant and clinical personnel blinding and at unclear risk of bias for selective outcome reporting (Table 2). Additionally, trial protocols were generally not available as many of the trials included in this review had been

published before the International Committee of Medical Journal Editors' (ICMJE) mandatory trial registration guidelines took effect in 2005 (De Angelis et al., 2004).

Four further trials (22.2%) were rated as at high risk of bias for outcome assessor blinding. In two cases this was because all outcomes relied on self-reported measures and participants themselves were not blind to treatment allocation (Guthrie et al., 2001; Slee et al., 2008), whilst in the remaining two cases, outcome assessor blinding could not be achieved due to feasibility limitations (Brown et al., 2005; Stewart et al., 2009). Performance and detection bias therefore cannot be ruled out for the majority of the trials included in this review.

One study (5.6%) was rated as at high risk of bias for allocation concealment as this study made use of Zelen's post-randomization consent procedure in which participants are asked to consent to inclusion in the trial after being notified to which group, intervention or TAU, they were allocated (Hatcher et al., 2011). Selection bias therefore cannot be ruled out.

In nine trials there were either no withdrawals from the study (Davidson et al., 2014; Gibbons et al., 1978; Guthrie et al., 2001; Hawton et al., 1987; Salkovskis et al., 1990; Weinberg et al., 2006), or, less than 10% of the participant pool could not be located at follow-up (Evans et al., 1999; Husain et al., 2014; Slee et al., 2008). In two trials (11.1%) either no information was provided on the amount of missing data at follow-up (Patsiokas and Clum, 1985), or, no apparent attempt was made to follow-up patients post-intervention (Stewart et al., 2009). In three further trials, although greater than 10% of the participant pool could not be located at the final follow-up assessment, nonetheless, appropriate measures were used to account for missing data (Brown et al., 2005; Hatcher et al., 2011; Wei et al., 2013). For the remaining four trials (38.9%), greater than 10% of the allocated participants could not be located at

the final follow-up assessment and no apparent attempt was made to statistically account for missing data (Dubois et al., 1999; McAuliffe et al., 2014; Tapolaa et al., 2010; Tyrer et al., 2003). Missing data were a greater concern for the TAU arm as compared to the intervention arm (weighted average 12.4% versus 8.4%).

Description of Treatment As Usual

The content of TAU for each of the studies is summarized in Table 3. In most studies a description of the TAU control condition was provided *a priori* (83.3%). For the majority of these trials TAU was multidisciplinary in nature, combining psychotherapy, pharmacotherapy, and referral to specialist services (e.g., personality disorder, addictions, and other services) as required (Davidson et al., 2014; Dubois et al., 1999; Evans et al., 1999; Gibbons et al., 1978; Guthrie et al., 2001; Hatcher et al., 2011; McAuliffe et al., 2014; Patsiokas and Clum, 1985; Slee et al., 2008; Stewart et al., 2009; Tapolaa et al., 2010; Tyrer et al., 2003; Weinberg et al., 2006). For two further trials TAU comprised referral to the participant's primary care physician (Hawton et al., 1987; Husain et al., 2014).

In two trials (11.1%), however, there was no description of the TAU condition (Salkovskis et al., 1990; Wei et al., 2013). In one further trial (5.6%) insufficient details of TAU content were provided (Brown et al., 2005). In line with previous work (Watts et al., 2015), we therefore categorized the TAU condition in these three trials as unclear.

Effect of Treatment As Usual Condition on Repetition of Self-Harm

As we have previously reported (Hawton et al., 2016a, b), CBT-based psychotherapy was associated with a significant reduction in the proportion of people

repeating self-harm at the final follow-up assessment in these trials (OR 0.70, 95% CI 0.55 to 0.88; p=0.003; Figure 2). However, sub-group analyses demonstrated that the TAU condition was significantly associated with variability in the finding regarding the effectiveness of CBT-based psychotherapy (χ^2=6.38, df=2, p=0.04, I^2=68.6%; Figure 2). Specifically, whilst CBT-based psychotherapy was strongly associated with a significant treatment effect for repetition of self-harm when compared to an unclear TAU condition (OR 0.29, 95% CI 0.13 to 0.62; 3 trials), the effect size was reduced when compared to multidisciplinary TAU (OR 0.79, 95% CI 0.63 to 0.97; 12 trials). CBT-based psychotherapy was not associated with a treatment effect for repetition of self-harm at this assessment point when compared to GP management (OR 053, 95% CI 0.15 to 1.93; two trials; Figure 2). However, it is important to note that only two trials were included in this latter sub-group and therefore the estimate of effect for this finding is imprecise.

Effect of Treatment As Usual Condition on Suicidal Ideation Scores

CBT-based psychotherapy was associated with a significant treatment effect for suicidal ideation scores at the final assessment point (SMD -0.28, 95% CI -0.47 to -0.09; p=0.003; Figure 3). There was no evidence of a significant difference in the effect size as a result of the TAU comparator condition used (χ^2=0.05, df=1, p=0.83; I^2=0%; Figure 3).

Effect of Treatment As Usual Condition on Depression Scores

CBT-based psychotherapy was associated with a significant treatment effect for depression scores at the final follow-up assessment (SMD -0.31, 95% CI -0.48 to -0.14; p=0.0003; Figure 4). Although the effect for CBT-based psychotherapy on

depression scores was strongest when compared against multidisciplinary TAU (SMD -0.35, 95% CI -0.58 to -0.12; 9 trials), followed by GP management (SMD -0.28, 95% CI -0.52 to -0.04; 2 trials), and non-significantly associated with a treatment effect for depression scores when compared to unclear TAU (SMD -0.33, 95% CI -0.94 to 0.28; 3 trials), these sub-group differences were not significant (χ^2=0.18, *df*=2, *p*=0.91, I^2=0%; Figure 4).

Effect of Treatment As Usual Condition on Hopelessness Scores

CBT-based psychotherapy was associated with a significant reduction in hopelessness scores at the final follow-up assessment (SMD -0.31, 95% CI -0.51 to -0.10; *p*=0.003; Figure 5). Although this effect appeared to be strongest when CBT-based psychotherapy was compared to an unclear TAU condition (SMD -0.68, 95% CI -1.80 to 0.43; 2 trials), in contrast to where TAU comprised either GP management (SMD -0.41, 95% CI -0.68 to -0.14; 1 trial) or multidisciplinary TAU (SMD -0.22, 95% CI -0.45 to 0.01; 4 trials), these subgroup differences were not significant (χ^2=1.61, *df*=2, *p*=0.45, I^2=0%; Figure 5).

DISCUSSION

We have previously shown that CBT-based psychotherapy is associated with significant post-treatment reductions in self-harm, depression, hopelessness, and suicidal ideation, but not suicide (although the number of events for this outcome was relatively small) (Hawton et al., 2016a, b). However, differences in the quality of the TAU comparator condition between trials still represents an important source of variability (Arensman et al., 2001). The aim of the present review, therefore, was to

highlight the potential impact of the TAU condition on estimates of treatment effects for these interventions and to provide reporting guidance for future trials in this area.

In few trials were details provided of the treatment components offered to participants allocated to the TAU condition. In fewer still was the number of treatment sessions attended by control participants reported. Additionally, and particularly importantly, no author provided a detailed break-down of the treatments actually received by participants in the TAU condition. This is in contrast to a recent report on an RCT of dialectical behaviour therapy for self-harm in adults which includes a supplementary table outlining the various treatments received by participants allocated to the TAU condition and the mean number of months the participants received each of these components (Priebe et al., 2012). We recommend that in future trials of psychosocial interventions for self-harm in which TAU is the control condition researchers should, where possible, aim to reproduce such tables to assist in calculating treatment dosage for participants allocated to the TAU arm.

Recommendations for TAU Treatment Conditions

Although in most trials included in this review some description of the content of the TAU condition was provided (83.3%), sub-group analyses suggested evidence of a significant difference in effectiveness for CBT-based psychotherapy for the primary outcome measure, repetition of self-harm, for those studies in which TAU content was not adequately described. However, it should be noted that, generally, for those trials in which TAU content was not clearly described they were also rated as being or poor quality in other aspects of trial design. Thus, we cannot we clear if this finding is specific to description of TAU content, or a more global consequence of trial design. Also, given that components of CBT-based psychotherapy may have

come to be integrated into TAU across a number of services internationally, this finding may also be partly explained by potential similarities between the CBT-based psychotherapy treatment condition and the TAU condition. However, this cannot be verified at the present time due to limited information on TAU content in many of the included studies.

For the secondary outcome measure of depression scores, in contrast, we found a non-significant trend towards stronger effects for CBT-based psychotherapy when compared to multidisciplinary TAU as compared to when TAU content was not adequately described. However, the effect for hopelessness scores was consistent with that observed for repetition of self-harm. As no studies that reported outcome data for suicidal ideation scores were rated as unclear TAU, we were unable to investigate the impact of an unclear TAU condition on the magnitude of the effect size for this outcome.

In none of the included trials were there clear descriptions of the treatment components (e.g., psychotherapy, pharmacotherapy, welfare) available to participants assigned to the TAU condition and the number of participants that received each of these. We suggest that in future trials researchers should where possible provide details on the type(s) of treatments available to participants assigned to the TAU group, the number of patients in the TAU condition who received each component(s) and the number of patients involved in follow-up assessments. The number and frequency of contacts with each component(s) should also be specified where possible. We acknowledge, however, that it may not always be possible to record details on the treatment received by participants assigned to the TAU group to the same level of detail as for those assigned to the intervention group due to budgetary and other considerations. Further detail on the component(s) of TAU actually

received, however, will help to determine whether the TAU condition reflects current clinical best-practice for the treatment setting, and whether the TAU condition controlled for any non-specific effect(s) of the intervention condition.

For one trial in which the intervention treatment was offered in a group-based format, TAU involved referral for predominately individual-based psychotherapy (McAuliffe et al., 2014). Offering psychotherapy in a group-based environment may provide a number of additional beneficial effects beyond the hypothesized mechanism of change for this intervention, such as helping participants overcome social isolation. Alternatively, offering treatment in a group-based format may be detrimental for this patient group, given findings from one Australian trial of group-based CBT with adolescent self-harm patients in which information shared during a group-based psychotherapy session was posted on a participant's personal web-blog (Hazell et al., 2009). There may also be more detrimental effects of group-based CBT when self-harm patients with a history of frequent self-harm repetition are involved, as they may be particularly vulnerable to the social contagion effects of self-harm (Haw et al., 2013).

Strengths and Limitations

The primary strength of this review relates to the systematic approach used to identify and include data from all relevant trials and the extent to which most of them include detailed information on content of therapy and outcomes. In all trials there were far more details of the experimental treatment compared to TAU. The included trials all had risk of bias in that they were rated as at high risk of bias with respect to participant and clinical personnel blinding and at unclear risk of bias for selective outcome reporting. In part, however, this reflects the fact that the trials included in

this review examined the effectiveness of psychotherapy and it is generally not possible to blind either the participants themselves, or the therapists delivering treatment, to psychological therapy. There was also considerable variability in the proportion of participants for whom follow-up information on the primary outcome measure, repetition of self-harm, was lacking, ranging from 0% for six studies to over half (63.2%) for one study. In the main this likely reflects differences in the approach used to ascertain repetition. For those studies in which repetition of self-harm was ascertained from medical and/or hospital records, rates of missing data were lower than in those in which self-reported information was used as these data would only have been available for those able to be located at follow-up and may additionally have been affected by recall and other biases.

Conclusions

The present review suggests that whilst, overall, CBT-based psychotherapy was more effective than TAU in reducing the proportion of participants who self-harm and also depression, hopelessness and suicidal ideation at final follow-up, results varied by TAU content. Specifically, effects in favour of CBT-based psychotherapy in reducing repetition of self-harm were strongest where the TAU was not clearly described. The study shows that TAU content and quality is a significant, but infrequently investigated, source of heterogeneity between trials of interventions for the prevention of self-harm and, furthermore, that TAU is not a homogenous comparator. We suggest that in future, researchers in this field should carefully describe both the nature of TAU and what participants in this condition actually received in order to improve the overall quality of trials of psychological interventions and the interpretation of the findings for application in treatment services.

Role of the Funding Source: This review received no specific source of external funding. KH used personal funding received from the National Institute for Health Research (NIHR) to support the project. The NIHR had no role in the research or the decision to publish. The views expressed are those of the author(s) and not necessarily those of the NIHR.

Contributions

KH had the idea for this article. All authors extracted data and assessed risk of bias for included trials. KW and TTS conducted the statistical analyses. KW and KH wrote the initial version of the article. All authors contributed to the interpretation of results and revisions of the article and also approved the final version for publication.

Conflict of Interests

KH authored two of the trials included in this article, and EA, DG, PH, and KVH authored one trial each. We declare no other competing interests.

Acknowledgements

The authors wish to acknowledge the help of all authors who provided additional clarification and/or extra data for their trials.

Table 1. Methodological details of the 18 trials of CBT included in this review.

Study	Country	N		Age	Female	History of self-harm	Participant Source	Treatment Duration	*N* (%) Lacking Follow-Up Information[1]	Measures	Risk of Bias
		INV	*CTL*	*(SD)*	(%)	(%)					
Brown et al., 2005	USA	60	60	35.0 (*10.3*)	60.8	72.5	Patients presenting to hospital following a suicide attempt.	Between 10-20 weeks.	35/120 *(20.8%)*	*Self-harm:* self-reported. *Depression:* Beck Depression Inventory (BDI) and Hamilton Rating Scale for Depression (HAM-D). *Hopelessness:* Beck Hopelessness Scale (BHS) *Suicidal ideation:* Beck Scale for Suicidal Ideation (BSSI), dichotomised. *Suicide:* NR.	Participants, clinical personnel, and outcome assessors not blind to allocation.
Davidson et al., 2014	UK	14	6	NR	NR	NR	Patients admitted to	NR.	0/772	*Self-harm:* self-reported according to	Nature of trial suggests participants

							the medical ward of local accident and emergency departments following an episode of self-harm.		*(0.0%)*	the Acts of Deliberate Self-Harm Inventory. *Depression:* Hospital Anxiety and Depression Rating Scale (HADRS). *Suicidal Ideation:* BSSI. *Suicide:* NR.	and clinical personnel not blind to allocation. Imbalance between intervention and control groups in terms of history of previous self-harm, anxiety, and depression scores. Authors did not adjust for these differences in their analyses.
Dubois et al., 1999	France	51	51	22.3 *(5.8)*	80.4	NR	Patients attending any emergency department following self-harm.	1 month.	18/102 *(17.6%)*	*Self-harm:* NR. *Suicide:* NR.	Nature of trial suggests participants and clinical personnel not blind to allocation. Unclear if outcome assessor also bind to allocation. Less than two-thirds of participants in the intervention group attended all three treatment sessions.
Evans et al., 1999	UK	18	16	NR	61.8	100.0	Patients admitted to general hospitals following an episode of self-harm.	6 months.	2/34 *(5.9%)*	*Self-harm:* self-report according to the Linehan Parasuicide History Interview, supplemented by hospital records. *Depression:* HADRS.	Nature of trial suggests participants and clinical personnel not blind to allocation. Five participants in the intervention group did not see a therapist and instead received bibliotherapy whilst one further participant received no intervention.
Gibbons et al., 1978	UK	200	200	NR	71.0	NR	Patients presenting to accident and emergency departments following an episode of self-poisoning.	3 months.	0/400 *(0.0%)*	*Self-harm:* hospital and/or medical records. *Depression:* BDI. *Problem-solving:* self-report.	Nature of trial suggests participants and clinical personnel not blind to allocation.
Guthrie et al., 2001	UK	58	61	31.2 *(1.5)*	54.6	59.7	Patients presenting to hospital following an episode of self-poisoning.	4 weeks.	0/119 *(0.0%)*	*Self-harm:* self-report supplemented by medical records. *Depression:* BDI scores. *Suicidal ideation:* BSSI. *Suicide:* NR.	Nature of trial suggests participants and clinical personnel not blind to allocation. Although outcome assessors blind to allocation, data on repetition of SH obtained from self-report.
Hatcher et al., 2011	NZ	253	299	33.7 *(12.9)*	68.8	44.7	Patients admitted to hospital following an episode of self-harm.	3 months.	158/1094 *(14.4%)*	*Self-harm:* hospital records. *Depression:* HADRS. *Hopelessness:* BHS. *Suicidal ideation:* BSSI. *Problem-solving:* Social Problem Solving Inventory, Revised (SPS-R). *Suicide:* Coroners' records.	Nature of trial suggests participants not blind to allocation. Clinical personnel not blind to allocation.
Hawton et al., 1987	UK	41	39	29.3 *(NR)*	66.3	31.2	Patients admitted to a general hospital following an episode of self-poisoning.	NR.	0/80 *(0.0%)*	*Self-harm:* self-report, supplemented by hospital and medical records. *Depression:* BDI. *Problem-solving:* self-report. *Suicide:* collateral informant report.	Nature of trial suggests participants and clinical personnel not blind to allocation.
Husain et al., 2010	Pakistan	108	113	23.1 *(5.5)*	68.8	4.1	Patients admitted to the medical unit of a university hospital following an episode	3 months.	8/221 *(3.6%)*	*Self-harm:* self-report according to the Suicide Attempt Self-Injury Interview. *Depression:* BDI.	Participants and clinical personnel not blind to allocation.

							of self-harm.			*Hopelessness:* BHS. *Suicidal ideation:* BSSI. *Problem-solving:* Coping Resource Inventory (CRI). *Suicide:* NR.	
McAuliffe et al., 2014	Republic of Ireland	222	211	33.5 *(11.8)*	29.8	29.3	Admissions to emergency departments or an acute psychiatric unit following an episode of self-harm.	6 weeks.	107/433 *(24.7%)*	*Self-harm:* self-report (at 6 weeks post-intervention and 6 months' follow-up) and hospital records (at 12 months' follow-up). *Depression:* BDI. *Hopelessness:* BHS. *Suicidal ideation:* BSSI. *Problem-solving:* Self-Rated Problem Solving Scale (SRPSS). *Suicide:* NR.	Participants and clinical personnel not blind to allocation.
Patsiokas & Clum, 1985	USA	10	5	NR	NR	NR	Admissions to a psychiatric ward following an episode of self-harm.	3 weeks.	N/A[2]	*Self-harm:* NR. *Hopelessness:* BHS. *Suicidal ideation:* BSSI and Self-Monitoring of Suicidal Ideation. *Problem-solving:* Means-Ends Problem-Solving (MEPS).	Nature of trial suggests participants and outcome assessors not blind to allocation. As same therapist delivered intervention and control therapies, clinical personnel also not blind to allocation.
Salkovskis et al., 1990	UK	12	8	27.2 *(6.7)*	50.0	100.0	Referrals from the duty psychiatrist following an episode of self-poisoning involving antidepressants that necessitated admission to an accident and emergency department.	1 month.	0/20 *(0.0%)*	*Self-harm:* hospital records. *Depression:* BDI. *Hopelessness:* BHS. *Suicidal ideation:* BSSI. *Problem-solving:* Personal Questionnaire Rapid Scaling Technique. *Suicide:* NR.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation.
Slee et al., 2008	The Netherlands	40	42	24.7 *(5.5)*	93.9	NR.	Admissions to emergency departments or mental health centres.	5.5 months.	8/90 *(8.9%)*	*Self-harm:* self-report. *Depression:* BDI. *Suicidal ideation:* Suicide Cognition Scale. *Problem-solving:* Coping Inventory for Stressful Situations. *Suicide:* NR.	Participants, clinical personnel, and outcome assessors not blind to allocation. Of the 90 participants randomized, eight did not receive the intervention. Reasons for this were not stated.
Stewart et al., 2009	Australia	23	9	NR	53.1	NR	Admissions to hospital following an episode of self-harm.	2 months.	NR	*Self-harm:* hospital records. *Hopelessness:* BHS. *Suicidal ideation:* BSSI. *Problem-solving:* SPS-R. *Suicide:* NR.	Participants, clinical personnel, and outcome assessors not blind to allocation. Data only collected on treatment completers.
Tapolaa et al., 2010	Finland	9	7	33.2 *(NR)*	100.0	NR	Admissions to emergency departments following an episode of self-harm.	4 weeks.	3/16 *(18.7%)*	*Self-harm:* self-report according to the SASII. *Depression:* BDI. *Suicide:* NR.	Nature of trial suggests participants and outcome assessors not blind to allocation. Outcome assessor not blind to allocation. Data only collected on treatment completers.
Tyrer et al., 2003	UK	239	241	32.0 *(11.0)*	67.9	NR	Admissions to hospital following an episode of self-harm.	Between 3 and 6 months.	50/480 *(10.4%)*	*Self-harm:* self-report supplemented by medical records. *Depression:* HADRS. *Suicide:* Coroners' records.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation.

Wei et al., 2013	China	82	77	31.8 *(12.9)*	73.5	NR	Admissions to emergency departments following an episode of self-harm.	3 months.	151/239 *(63.2%)*	*Self-harm:* self-report. *Depression:* HAM-D. *Suicidal ideation:* BSSI. *Suicide:* collateral informant report.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation.
Weinberg et al., 2006	USA	15	15	28.2 *(8.2)*	100.0	NR	Community referrals following an episode of self-harm.	2 months.	0/30 *(0.0%)*	*Self-harm:* self-report according to the SASII. *Depression:* HAM-D. *Suicidal ideation:* Suicide Behaviors Questionnaire, suicidal ideation subscale. *Suicide:* NR.	Nature of trial suggests participants, clinical personnel, and outcome assessors not blind to allocation.

Table Notes: NR: not reported; NZ: New Zealand; UK: United Kingdom; USA: United States of America.
[1] Proportion (%) missing data for the primary outcome, repetition of self-harm at the final follow-up assessment.
[2] Proportion (%) missing data not reported for this trial cannot be ascertained as data for repetition of self-harm was not reported.

Table 2: Summary of Risk of bias for the included studies according to the Cochrane Risk of Bias Tool.

Study	Risk of Bias Domains						
	Random Sequence Generation	*Allocation Concealment*	*Participant Blinding*	*Clinical Personnel Blinding*	*Outcome Assessor Blinding*	*Incomplete Outcome Data*	*Selecting Reporting*
Brown et al., 2005	Low	Unclear	High	High	High	Low	Unclear
Davidson et al., 2014	Low	Unclear	High	High	Low	Low	Unclear
Dubois et al., 1999	Unclear	Unclear	High	High	Unclear	High	Unclear
Evans et al., 1999	Unclear	Low	High	High	Low	Low	Unclear
Gibbons et al., 1978	Low	Low	High	High	Low	Low	Unclear
Guthrie et al., 2001	Low	Low	High	High	High	Low	Unclear
Hatcher et al., 2011	Low	High	High	High	Low	Low	Unclear
Hawton et al., 1987	Low	Low	High	High	Low	Low	Unclear
Husain et al., 2010	Low	Low	High	High	Low	Low	Unclear
McAuliffe et al., 2014	Low	Low	High	High	Low	High	Unclear
Patsiokas & Clum, 1985	Unclear	Unclear	High	High	Unclear	Unclear	Unclear
Salkovskis et al., 1990	Low	Low	High	High	Unclear	Low	Unclear
Slee et al., 2008	Low	Low	High	High	High	Low	Unclear
Stewart et al., 2009	Low	Unclear	High	High	High	Unclear	Unclear
Tapolaa et al., 2010	Low	Unclear	High	High	Unclear	High	Unclear
Tyrer et al., 2003	Low	Low	High	High	Unclear	High	Unclear
Wei et al., 2013	Low	Unclear	High	High	Unclear	Low	Unclear
Weinberg et al., 2006	Low	Low	High	High	Low	Low	Unclear

Table 3. Treatment as usual (TAU) definition and classification for the 18 studies included in this review.

Study	TAU Content and Quality Description	TAU Classification
Brown et al., 2005	"Participants in both study groups received usual care from clinicians in the community as well as tracking and referral services…" (p.565).	Unclear/Not Described
Davidson et al., 2014	"Treatment as usual (TAU) was referral to a community mental health team and included appointments from a psychiatrist and community psychiatric nurse. In-patient treatment was given when required" (p.109).	Multiple Providers
Dubois et al., 1999	"[Le] cohort 'témoin' bénéficie d'une prise en charge classique…d'un entretien cliniquepsychiartique et à la sortie de l'hôpital d'une orientation aspécidique vers un suivi psychiatrique or psychologique" (p.558). [The usual care cohort received traditional care…an assessment by a clinical psychiatrist and, on leaving the hospital, were followed-up by a psychiatrist or psychologist].	Multiple Providers
Evans et al., 1999	"Patients allocated to TAU received the standard psychiatric treatment for their condition with no restrictions apart from the use of the experimental treatment. This included in-patient psychiatric treatment, out-patient care, day hospital care and community treatment" (p.21).	Multiple Providers
Gibbons et al., 1978	"[Control] patients received the routine service: referral back to a G.P. (54 per cent); psychiatric referral (33 per cent); and other referral (13 per cent)" (p.113).	Multiple Providers
Guthrie et al., 2001	"Patients who were randomised to the 'treatment as usual' arm received routine care. In most cases this consists of an assessment by a casualty doctor or junior psychiatrist in the emergency department, on the basis of which about one third patients are referred for follow up as a psychiatry outpatient, a small number are referred to addiction services, and the remainder are advised to consult their own general practitioner. No patients are routinely referred to psychotherapy of psychology services" (p.2).	Multiple Providers
Hatcher et al., 2011	"Usual care following self-harm varies and may involve referral to multidisciplinary teams for psychiatric or psychological intervention, referral to mental health crisis teams, recommendations for engagement with alcohol and drug treatment centres or other health and non-health services." (p.311).	Multiple Providers
Hawton et al., 1987	"[Treatment as usual involved d]ischarge summaries sent by the counsellors to the general practitioners [and] included recommendations for them to provide or arrange further care (e.g., marital therapy, individual support)…patients in either treatment group were [also] offered telephone 'open access' to the general hospital psychiatric service…" (p.752).	GP Management.
Husain et al., 2010	"Local medical, psychiatric and primary care services provided standard routine care. Participants received an initial assessment along with TAU as ascertained by their treating doctor or their primary care physician (general practitioner, GP). Patients are not routinely referred to psychiatric or psychology services." (p.464).	GP Management
McAuliffe et al., 2014	"Treatment as usual involved assessment by mental health professional staff and by crisis nurses. Psychosocial assessment of all [TAU] patients was carried out by a psychiatrist (liaison psychiatry or mental health team) to determine mental health needs and level of risk to self or others. Patients who had no contact with mental health services during the previous year and not requiring referral on to mental health acute or community-based services were referred to the crisis nurse service for further psychosocial assessment and suicide risk assessment…Those who were referred on by the psychiatrist to mental health acute or community-based services were commonly offered pharmacological treatment and review by the mental health team and less frequently counselling or psychotherapy" (p.385).	Multiple Providers
Patsiokas & Clum, 1985	"Nondirective control…The subjects in this group had individual sessions in which an open discussion occurred on their suicidal behaviour, problems, and daily lives" (p.283).	Psychotherapy Only
Salkovskis et al., 1990	" 'Treatment as usual' was used as the comparison group…" (p.872).	Unclear/Not Described
Slee et al., 2008	"We recorded three forms of TAU: psychotropic medication, psychotherapy and psychiatric hospitalisations." (p.205).	Multiple Providers
Stewart et al., 2009	"Community follow-up was offered by the respective HSDs Acute Care Team (ACT) and formed the treatment as usual (TAU) condition for the purpose of the current study. Follow-up consisted of telephone calls, home visits, appointments with the psychiatrist, liaison with the client's general practitioner, or networking with social supports" (p.539).	Multiple Providers
Tapolaa et al., 2010	"We recorded three forms of TAU: psychotropic medication, psychiatric hospitalization, and outpatient sessions with a mental health worker (not a qualified psychotherapist)" (p.99).	Multiple Providers
Tyrer et al., 2003	"Patients allocated to TAU were seen by another designated therapist and offered the standard treatment in the area concerned or the continuation of this if already implemented; this varied from problem solving approaches…dynamic psychotherapy…GP or voluntary group referral…or short-term counselling" (p.970).	Psychotherapy Only
Wei et al., 2013	"Patients in the control group did not receive any interventions" (p.109).	Unclear/Not Described
Weinberg et al., 2006	"TAU included 5 patients treated by a psychiatrist, 3 by a community mental health worker, 4 by a social worker, and 2 who received no treatment. No information was reported on treatment for the remaining two TAU participants" (p.483).	Multiple Providers

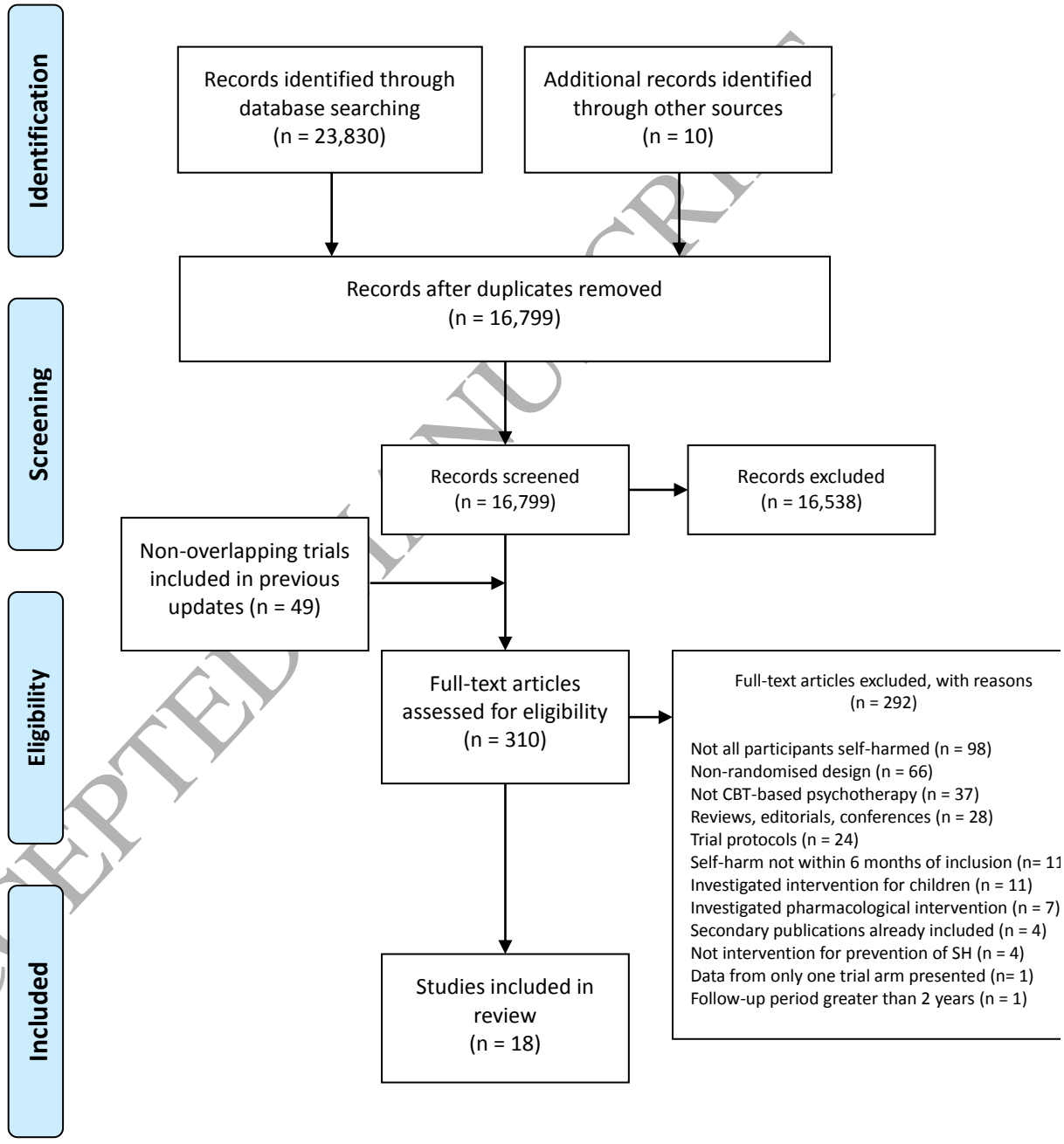


Figure 1. PRISMA flow diagram of included and excluded studies for this version of the review.

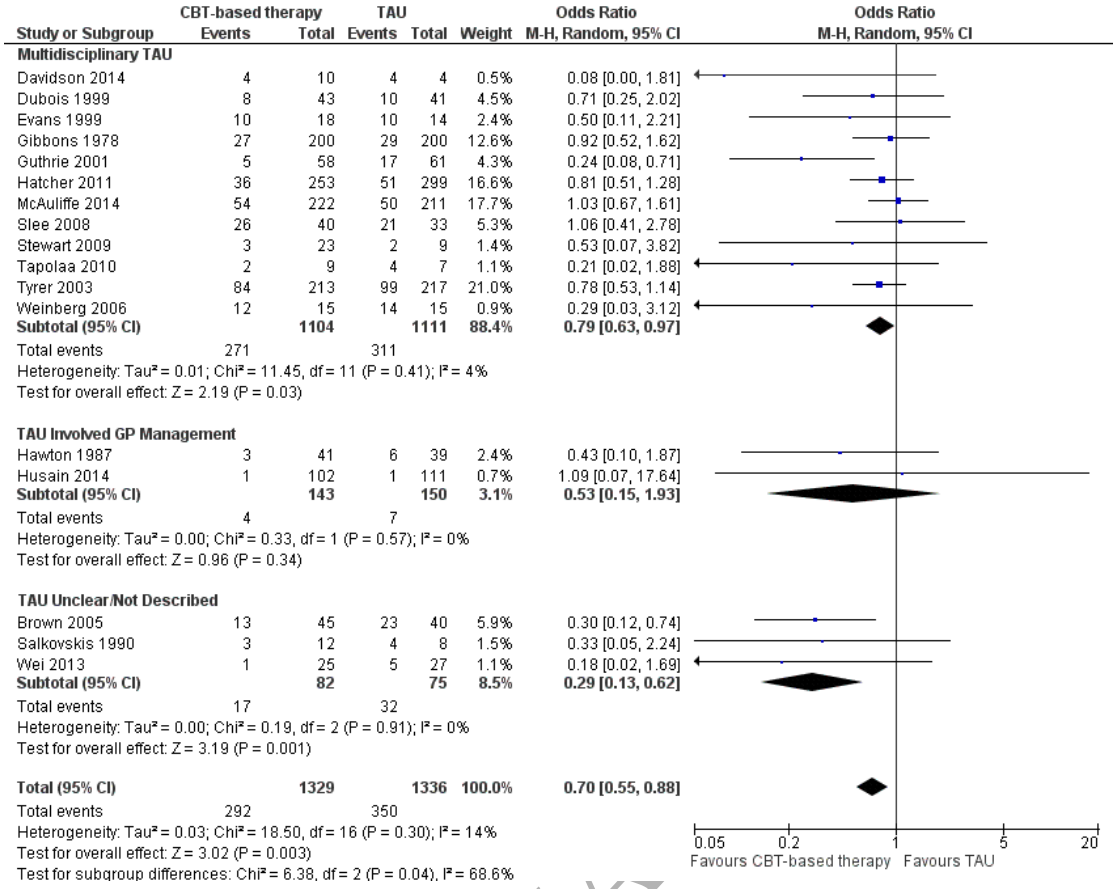


Figure 2. Random effects odds ratio (OR) and 95% confidence interval (CI) for repetition of self-harm at the final follow-up assessment sub-grouped according to TAU condition.

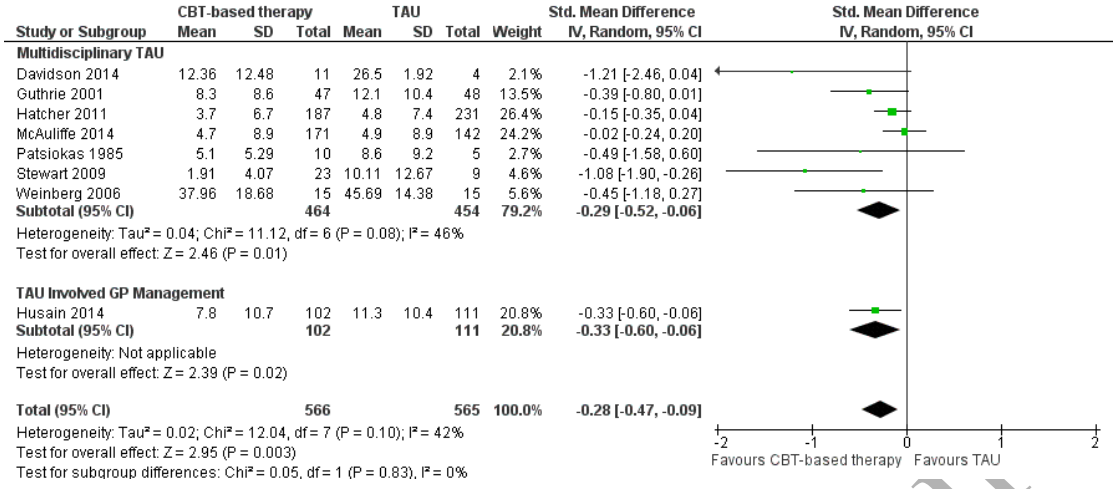


Figure 3. Random effects standard mean difference (SMD) and 95% confidence interval (CI) for suicidal ideation scores at final follow-up sub-grouped according to TAU condition.

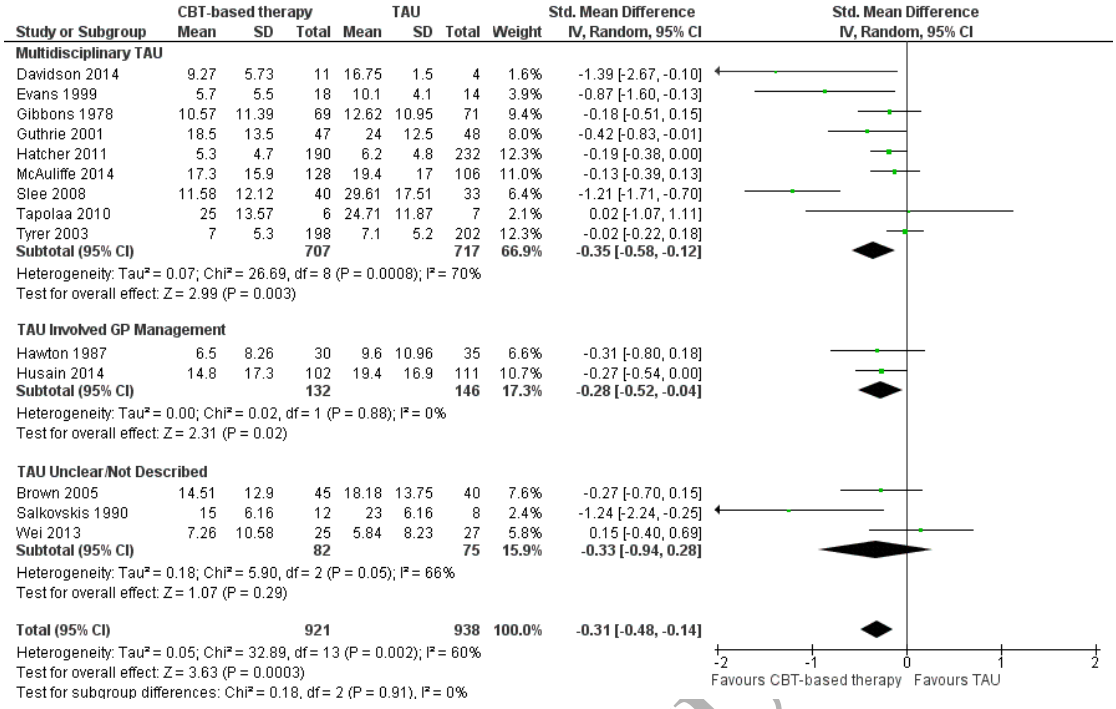


Figure 4. Random effects standard mean difference (SMD) and 95% confidence interval (CI) for depression scores at final follow-up sub-grouped according to TAU condition.

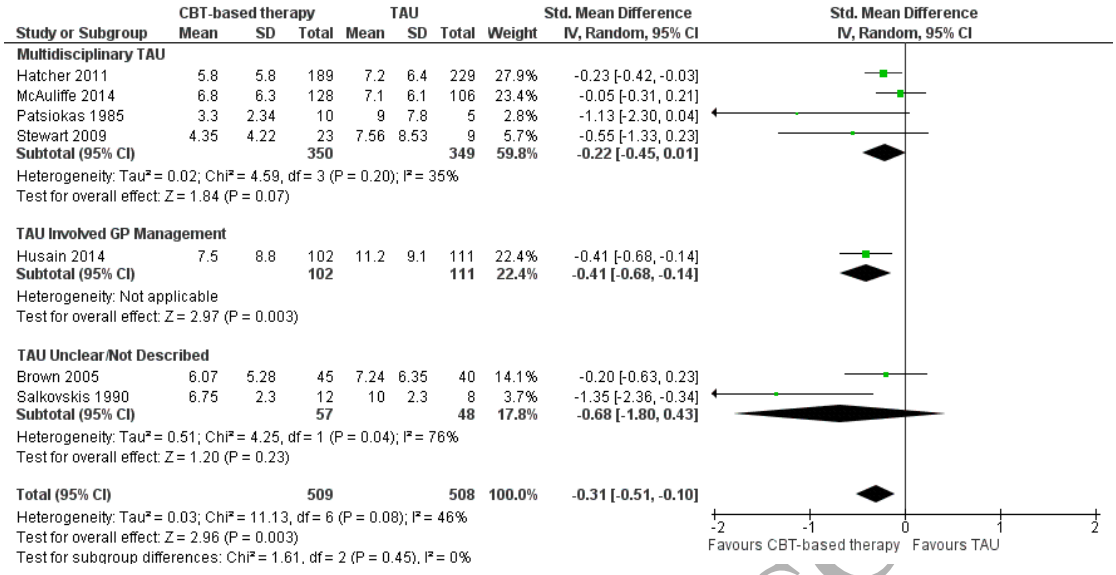


Figure 5. Random effects standard mean difference (SMD) and 95% confidence interval (CI) for hopelessness scores at final follow-up sub-grouped according to TAU condition.

REFERENCES

Abraha, I., Cherubini, A., Cozzolino, F., De Florio, R., Luchetta, M., Rimland, J., Folletti, I., Marchesi, M., Germani, A., Orso, M., Eusebi, P., Montedori, A., 2015. Deviation from intention to treat analysis in randomised trials and treatment effect estimates: Meta-epidemiological study. BMJ 350, h2445.

Arensman, E., Townsend, E., Hawton, K., Bremner, S., Feldman, E., Goldney, R., Gunnell, D., Hazell, P., Van Heeringen, K., House, A., Owens, D., Sakinofsky, I., Träskman-Bendz, L., 2001. Psychosocial and pharmacological treatment of patients following deliberate self-harm: The methodological issues involved in evaluating effectiveness. Suicide Life Threat Behav 31, 169-180.

Brown, G., ten Have T, Henriques, G., Xie, S., Hollander J, Beck, A., 2005. Cognitive therapy for the prevention of suicide attempts: A randomized controlled trial. J Am Med Assoc 294, 563–570.

Burns, T., 2009. End of the road for treatment-as-usual studies? Br J Psychiatry 195, 5-6.

Burns, T., Priebe, S., 1996. Mental health care systems and their characteristics: A proposal. Acta Psychiatrica Scand 94, 381-385.

Carroll, R., Metcalfe, C., Gunnell, D., 2014. Hospital presenting self-harm and risk of fatal and non-fatal repetition: Systematic review and meta-analysis. PLoS One 9, e89944.

Clarke, G., Herinckix, H., Kinney, R., Paulson, R., Cutler, D., Lewis, K., Oxman, E., 2000. Psychiatric hospitalizations, arrests, emergency room visits, and homelessness of clients with serious and persistent mental illness: Findings from a randomized trial of two ACT programs vs. Usual care. Mental Health Services Research 2, 155-164.

Cooper, K., Chatters, R., Kaltenthaler, E., Wong, R., 2015. Psychological and psychosocial interventions for cannabis cessation in adults: A systematic review short report. Health Technol Assess 19, 56.

Craig, P., Dieppe, P., Macintyre, S., Mitchie, S., Nazareth, I., Petticrew, M., 2008. Developing and evaluating complex interventions: The new Medical Research Council guidance. BMJ 337, a1655.

Davidson, K., Brown, T., James, V., Kirk, J., Richardson, J., 2014. Manual-assisted cognitive therapy for self-harm in personality disorder and substance misuse: A feasibility trial. Psychiatr Bull 38, 108–111.

De Angelis, C., Drazen, J., Frizelle, F., Haug, C., Hoey, J., Horton, R., Kotzin, S., Laine, C., Marusic, A., Overbeke, J., Schroeder, T., Sox, H., Van der Weyden, M., 2004. Clinical trial registration: A statement from the International Committee of Medical Journal Editors. N Engl J Med 351, 1250-1251.

Dubois, L., Walter, M., Bleton, L., Genest, P., Lemonnier, E., Lachevre, G., 1999. Evaluation comparative et prospective d'un protocole de prise en charge specifique de jeunes suicidants: Analyse du diagnostic psychiatrique initial, de l'observance therapeutique et du taux de recidive a un an (resultats preliminaires) [Evaluation of a comparative and prospective protocol for suicidal youth: Analysis of psychiatric diagnosis, therapeutic compliance and rate of recurrence over one year (preliminary results)] Annales Medico-Psychologiques 157, 557–561.

Engles, J., Diehr, P., 2003. Imputation of missing longitudinal data: A comparison of methods. J Clin Epidemiol 56, 968-976.

Evans, K., Tyrer, P., Catalan, J., Schmidt, U., Davidson, K., Dent, J., Tata, P., Thornton, S., Barber, J., Thompson, S., 1999. Manual-assisted cognitive-behaviour therapy (MACT): A randomized controlled trial of a brief intervention with bibliotherapy in the treatment of recurrent deliberate self-harm. Psychol Med 29, 19–25.

Gibbons, J., Butler, J., Urwin, P., Gibbons, J., 1978. Evaluation of a social work service for self-poisoning patients. Br J Psychiatry 133, 111–118.

Guthrie, E., Kapur, N., Kway-Jones, K., Chew-Graham, C., Moorey, J., Mendel, E., Marino-Francis, F., Sanderson, S., Turpin, C., Boddy, G., Tomenson, B., 2001. Randomised controlled trial of brief psychological intervention after deliberate self poisoning. Br J Psychiatry 323, 135–138.

Hatcher, S., Sharon, C., Parag, V., Collins, N., 2011. Problem-solving therapy for people who present to hospital with self-harm: Zelen randomised controlled trial. Br J Psychiatry 199, 310–316.

Haw, C., HAwton, K., Niedzwiedz, C., Platt, S., 2013. Suicide clusters: A review of risk factors and mechanisms. Suicide Life Threat Behav 43, 97-108.

Hawton, K., Bergen, H., Casey, D., Simkin, S., Palmer, B., Cooper, J., Kapur, N., Horrocks, J., House, A., Lilley, R., Noble, R., Owens, D., 2007. Self-harm in England a tale of threee cities: Multicentre Study of Self-Harm. Soc Psychiatry Psychiatr Epidemiol 42, 513-521.

Hawton, K., Harriss, L., Hall, S., Simkin, S., Bale, E., Bond, A., 2003. Deliberate self-harm in Oxford, 1990-2000: A time of change in patient characteristics. Psychol Med 33, 987-995.

Hawton, K., McKeown, S., Day, A., Martin, P., O'Connor, M., Yule, J., 1987. Evaluation of out-patient counselling compared with general practitioner care following overdoses. Psychol Med 17, 751–761.

Hawton, K., Witt, K., Taylor Salisbury, T., Arensman, E., Gunnell, D., Hazell, P., Townsend, E., van Heeringen, K., 2016a. Psychosocial interventions following self-harm in adults: a systematic review and meta-analysis. Lancet Psychiatry 3, 740-750.

Hawton, K., Witt, K., Taylor Salisbury, T., Arensman, E., Gunnell, D., Hazell, P., Townsend, E., van Heeringen, K., 2016b. Psychosocial interventions for self-harm in adults. Cochrane Database of Systematic Reviews 5, CD012189.

Hazell, P., Martin, G., McGill, K., Kay, T., Wood, A., Trainor, G., 2009. Group therapy for repeated deliberate self-harming adolescents: Failure of replication of a randomized trial. J Am Acad Child Adolesc Psychiatry 48, 662-670.

Higgins, J., Deeks, J., Altman, D., 2008a. Analysing data and undertaking meta-analyses, In: Higgins, J., Green, S. (Eds.), Cochrane Handbook for Systematic Reviews of Interventions. John Wiley & Sons, Chichester, UK, pp. 243-296.

Higgins, J., Deeks, J., Altman, D., 2008b. Assessing risk of bias in included studies, In: Higgins, J., Green, S. (Eds.), Cochrane Handbook for Systematic Reviews of Interventions. John Wiley & Sons, Chichester, UK, pp. 187-242.

Higgins, J., Deeks, J., Altman, D., 2011. Special topics in statistics: Intention-to-treat issues for continuous data, In: Higgins, J., Green, S. (Eds.), Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0. The Cochrane Collaboration, Available from: www.handbook.cochrane.org.

Higgins, J., Thompson, S., Deeks, J., Altman, D., 2003. Measuring inconsistency in meta-analysis. BMJ 327, 557-563.

Hollis, S., 1999. What is meant by intention to treat analysis? Survey of published randomised controlled trials. BMJ 319, 670.

Husain, N., Afsar, S., Ara, J., Fayyaz, H., ur Rahman, R., Tomenson, B., Hamirani, M., Chaudhry, N., Fatima, B., Husain, M., Naeem, F., IB, C., 2014. Brief psychological intervention after self-harm: Randomised controlled trial from Pakistan. Br J Psychiatry 204, 462–470.

McAuliffe, C., McLeavey, B., Fitzgerald, T., Corcoran P, Carroll B, Ryan L, O'Keeffe B, Fitzgerald E, Hickey P, O'Regan M, Mulqueen J, E, A., 2014. Group problem-solving skills training for self-harm: Randomised controlled trial Br J Psychiatry 204, 383–390.

NICE, 2011. Self-Harm: Longer-term Management. Clinical Guideline 133. National Institute for Health and Clinical Excellence, London, UK.

Owens, D., Horrocks, J., House, A., 2002. Fatal and non-fatal repetition of self-harm: Systematic reivew. Br J Psychiatry 181, 193-199.

Patsiokas, A., Clum, G., 1985. Effects of psychotherapeutic strategies in the treatment of suicide attempters. Psychotherapy: Theory, Research and Practice 22, 281–290.

Priebe, S., Bhatti, N., Barnicot, K., Bremmer, S., Gaglia, A., Katsakou, C., Molosankwe, I., McCrone, P., Zinkler, M., 2012. Effectiveness and cost-effectiveness of dialectical behaviour therapy for self-harming patients with personality disorder: A pragmatic randomised controlled trial. Psychother Psychosom 81, 356-365.

Salkovskis, P., Atha, C., Storer, D., 1990. Cognitive-behavioural problem solving in the treatment of patients who repeatedly attempt suicide. A controlled trial. Br J Psychiatry 157, 871–876.

Sarin, F., Wallin, L., Widerlöv, B., 2011. Cognitive behavior therapy for schizophrenia: A meta-analytical review of randomized controlled trials. Nord J Psychiatry 65, 162-174.

Saunders, K., Smith, K., 2016. Interventions to prevent self-harm: What does the evidence say? Evid Based Mental Health 19, 69-72.

Slee, N., Garnefski, N., van der Leeden, R., Arensman, E., Spinhoven, P., 2008. Cognitive-behavioural intervention for self-harm: Randomised controlled trial. Br J Psychiatry 192, 202–211.

Stewart, C., Quinn, A., Plever, S., Emmerson, B., 2009. Comparing cognitive behavior therapy, problem solving therapy, and treatment as usual in a high risk population. Suicide Life Threat Behav 39, 538–547.

Tapolaa, V., Lappalainen, R., Wahlström, J., 2010. Brief intervention for deliberate self harm: An exploratory study. Suicidology Online 1, 95–108.

Tyrer, P., Thompson, S., Schmidt, U., Jones, V., Knapp, M., Davidson, K., Catalan, J., Airlie, J., Baxter, S., Byford, S., Byrne, G., Cameron, S., Caplan, R., Cooper, S., Ferguson, B., Freeman, C., Frost, S., Godley, J., Greenshields, J., Henderson, J., Holden, N., Keech, P., Kim, L., Logan, K., Manley, C., MacLeod, A., Murphy R, Patience L, Ramsay L, de Munroz S, Scott J, Seivewright H, Sivakumar K, Tata P, Thornton S, Ukoumunne OC, S, W., 2003. Randomized controlled trial of brief cognitive behaviour therapy versus treatment as usual in recurrent deliberate self-harm: The POPMACT study. Psychol Med 33, 969–976.

Van de Wiel, N., Matthys, W., Cohen-Kettenis, P., Maassen, G., Lochman, J., Van Engeland, H., 2007. The effectiveness of an experimental treatment when compared to care as usual depends on the type of care as usual. Behav Modification 31, 298-312.

Wampold, B., Budge, S., Laska, K., Del Re, A., Baardseth, T., Flükiger, C., Minami, T., Kivlighanm, D., Gunn, W., 2011. Evidence-based treatments for depression and anxiety versus treatment-as-usual: A meta-analysis of direct comparisons. Clin Psychol Rev 31, 1304-1312.

Watts, S., Turnell, A., Kladnitski, N., Newby, J., Andrews, G., 2015. Treatment-as-usual (TAU) is anything but usual: A meta-analysis of CBT versus TAU for anxiety and depression. J Affect Disord 175, 152-167.

Wei, S., Liu L, Bi B, Li H, Hou J, Tan S, Chen X, Chen W, Jia X, Dong G, Qin X, Y, L., 2013. An intervention and follow-up study following a suicide attempt in the emergency departments of four general hospitals in Shenyang, China. Crisis 34, 107–115.

Weinberg, I., Gunderson J, Hennen J, Cutter, C., 2006. Manual assisted cognitive treatment for deliberate self-harm in borderline personality disorder patients. J Personal Disord 20, 482–492.